

REMARKS

Claim 1 has been amended in this paper. Claim 4 has been cancelled. Upon entry of the within amendments, claims 1, 2, and 5-7 will be pending for further examination.

Claim 1 has been amended to more clearly define the subject matter of the present invention. More specifically, claim 1 has been amended to incorporate the limitation set forth in claim 4. As such, claim 4 has been cancelled without prejudice.

No new matter is added by virtue of the within amendments.

As an initial matter, it is believed the amendments may be properly entered at this time, i.e. after final rejection, pursuant to 37 CFR §1.116, because the amendments do not require a new search or raise any new issues, and they reduce issues for appeal. Indeed, it is respectfully submitted that the within amendments place the application in condition for allowance. Thus, entry of the amendments at this time is earnestly solicited.

Applicants respectfully request reconsideration and withdrawal of the rejections directed to claims 1, 2, and 5-7, all of which Applicants respectfully submit are in condition for allowance (per the discussion below).

Rejections under 35 U.S.C. §103(a)

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. §103(a) over Tsuruda *et al.* (WO 01/68061, also as U.S. 6,924,410; hereinafter as "Tsuruda"). The rejection is traversed.

Without conceding to the validity of the Examiner's allegation and solely for facilitating the prosecution of the present application, independent claim 1 has been

amended to further define the features of this invention. Applicants contend that Tsuruda fails to teach, suggest or predict the patch as recited in the claims as amended.

The present invention is directed to a patch comprising a polyester backing, of which the ultraviolet transmittance is not more than 2.0% under the condition of 3.0 mW/cm² of ultraviolet intensity. In contrast, Tsuruda teaches a single-layer backing having a light transmittance of not more than 15% under the condition of 0.14 mW/hr/cm² of ultraviolet intensity and at a temperature of 25° C (see column 4, lines 20-27 of Tsuruda). It is acknowledged that one example of Tsuruda reports achieving a phototransmission rate of 2% (see Table 1 of Tsuruda). Nonetheless, Applicants contend that the phototransmission measured in Tsuruda is different from the ultraviolet transmittance measured in this invention.

In the Action, the Examiner has asserted that the backings of Tsuruda would have a ultraviolet transmittance of not more than 2% if measured under the conditions of the present application. Applicants contend that there is no factual basis to support such an assertion. It is noted that the conditions to measure the phototransmission in Tsuruda and the current conditions to measure the UV transmittance are quite different, for example, the Tsuruda backing was irradiated by fluorescent lamps and sunlight lamps to observe the ultraviolet intensity, while the present backing was irradiated under a direct sunlight (see, e.g., lines 26-33 of col. 18 of Tsuruda and paragraph [0036] of the instant application). Further, the phototransmission in Tsuruda was measured under an ultraviolet intensity of 0.14 mW/hr/cm², while the UV transmittance of this application was measured under an ultraviolet intensity of 3.0 mW/cm². In view of these differences, Applicants submit that it would not be possible for a skilled artisan to predict the UV transmittance value for Tsuruda's backing measured under the conditions of this invention, based on its phototransmission value measured under completely different conditions.

Applicants further submit that Tsuruda does not teach or suggest any effect that the weight of backing may place on its ultraviolet transmittance, let alone a combination of the specific ultraviolet transmittance and the specific weight range (i.e., $100 \text{ g/m}^2 - 130 \text{ g/m}^2$) required for the backing in this invention. The Examiner has alleged that any difference between the phototransmission rate of Tsuruda's backing and the UV transmittance rate of the present backing could merely be due to differences in the weights (or the thicknesses) of the polyester material used (see page 9 of the Action). Applicants respectfully traverse.

Applicants note that the ultraviolet transmittance value is an important property of a patch, which can demonstrate fundamental differences among various patches. According to the preparation details for Example 2 and Comparative Example 2 of the instant application, the ultraviolet intensity and the weights of the two backings are the same. Nonetheless, the ultraviolet transmittance values achieved by these patches are quite different: the UV transmittance value for Example 2 is 1.38%, while the UV transmittance value for Comparative Example 2 is 2.83% (see paragraph [0069] of Applicants' specification). Despite the fact that these patches share certain properties, the patch of Example 2 and that of Comparative Example 2 are clearly different. Accordingly, Applicants submit that the specific combination of the ultraviolet absorbent and the weight of backings makes the instantly claimed patch patentably distinct over the cited art.

Further, Applicants submit that the ultraviolet transmittance lower than 2.0% is difficult to achieve. Although Tsuruda discloses a backing having a light transmittance of preferably not more than 15% at an ultraviolet intensity of about 0.14 mW/hr/cm^2 , Tsuruda does not teach or suggest any patch having a backing, of which the ultraviolet transmittance is not more than 2.0% under an ultraviolet intensity of about 3.0 mW/hr/cm^2 , let alone a patch having a combination of a specific UV transmittance

value, a specific ultraviolet absorbent and a specific weight requirement for the backing used (as recited in the instant claims).

Further, Applicants submit that the record shows no reason why one skilled in the art would modify Tsuruda to arrive at the present patch, wherein (1) a polyester backing having ultraviolet transmittance not more than 2.0% under the condition of 3.0 mW/cm² of ultraviolet intensity; (2) the weight of the polyester backing is between 100 g/m² – 130 g/m²; (3) a pressure-sensitive adhesive layer containing a nonsteroidal anti-inflammatory drug; and (4) the backing contains a hydroxyphenylbenzotriazole derivative represented by the general formula(1) as recited in the instant claim 1. In *Eisai Co., Ltd v. Dr. Reddy, Labs., Ltd*, 2007-1397, slip op. at 8 (Fed. Cir. Jul. 21, 2008)(“*Eisai*”), the CAFC stated that “KSR presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound.” (citing *Takeda Chem. Indus. v. Alphapharm Pty., Ltd*, 492 F.3rd 1350, 1357 (Fed. Cir. 2007))(and holding at 7, that the prior art taught compounds with flourine-substituted groups that increased lipophilicity, whereas “the record... shows no reason for a skilled artisan to begin with [a prior art compound] only to drop the very feature, the fluorinated substitute, that gave this advantageous property”).

Tsuruda thus fails to teach or suggest the subject matter of the present claims for at least the above reasons. By way of further explanation:

First, as previously discussed, Tsuruda and the present invention are directed to two fundamentally different patches, as evidenced by the different conditions of ultraviolet intensity used and different light transmittances (phototransmittance and ultraviolet transmittance) measured.

Second, Tsuruda fails to teach or suggest a patch comprising a backing, for which a specific combination of the UV transmittance value, the ultraviolet absorbent and the weight, is required (as directed in this invention);

Third, Tsuruda fails to furnish any motivation or suggestion to modify the preparation described therein to reach the present invention.

Fourth, the patches of the present invention have achieved desirable low ultraviolet transmittance value of the backing, while exhibiting excellent drug delivery effects even when exposed to the direct rays of the sun in a season of high ultraviolet dose (see page 4, lines 8-13 of the present application). At the claimed conditions, patches of the present invention may be suitably and favorably used for application of a nonsteroidal anti-inflammatory drug (NSAID) which is low in stability toward ultraviolet light. In addition, because of the superiority of the present invention, even when the pressure-sensitive adhesive layer contains no ultraviolet absorbent, there is no degradation of the pressure-sensitive adhesive layer and there is excellent stability and safety; this is due to the fact that there is no contact to the skin of the ultraviolet absorbent itself (see page 4, lines 13-20 of the present application). In contrast, Tsuruda does not teach or suggest any such effects being rendered by the specific combinations as presently claimed. Nor does Tsuruda provide any motivation or suggestion to achieve such technical effects. Indeed, because Tsuruda is dealing with a much lower ultraviolet dose and also because of different measuring conditions used, it would not be possible for a skilled artisan to arrive at the present claimed patch with the desirable technical results in view of Tsuruda's disclosure, nor would there be any motivation or suggestion in that regard.

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P §

2142. This is important as “impermissible hindsight must be avoided and the legal conclusion must be gleaned from the prior art.” *Id.* Four factual inquiries must be made: first, a determination of the scope and contents of the prior art; second, a determination of the differences between the prior art and the claims in issue; third, a determination of level of ordinary skill in the pertinent art; and fourth, an evaluation of evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Three criteria may be helpful in determining whether claimed subject matter is obvious under 103(a): first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach or suggest all the claim limitations. *KSR Int’l Co. v. Teleflex, Inc.* No 04-1350 (U.S. Apr. 30, 2007).

Applicants submit that neither Tsuruda nor the knowledge generally available to one of ordinary skill in the art teaches or suggests all the limitations of the instant claims (as above discussed). Further, there is no suggestion or motivation to modify the cited art to make the claimed invention, nor is there any reasonable expectation of success in the art to achieve the desirable results of the present invention.

In view thereof, Applicants submit that the present invention is patentable over Tsuruda. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a) are requested.

Claims 1 and 4 are rejected under 35 U.S.C. §103(a) over Tsuruda in view of Cordes *et al.* (WO 97/232,227; hereinafter “Cordes”). The rejection is traversed.

Applicants respectfully submit that the combined disclosures of Tsuruda and Cordes still fail to teach, suggest or predict the patches recited in the present claims.

Cordes is relied upon for its alleged disclosure of a polyester backing layer with about $96 \pm 5 \text{ g/m}^2$. However, the addition of Cordes is still insufficient to cure the

deficiencies in Tsuruda. As such, the combination of Tsuruda and Cordes cannot sustain the rejection. Applicants submit that the cited art fails to teach or suggest a patch with ultraviolet transmittance not more than 2.0% under the condition of 3.0 mW/cm² of ultraviolet intensity, and within the weight of 100 g/m² to 130 g/m² (as required for the present invention).

Moreover, Cordes does not disclose a polyester backing layer with a weight per area of 96 ± 5 g/m². It only discloses a film of a matrix weighing $96 \pm 5\%$ g/m² as dry weight and corresponding to 1.25 g estradiol and 8.32 g NETA per m² of the dry matrix. Applicants submit that "the weight of a film of a matrix" is a concept different from "the weight of backings." A person skilled in the art considers that a film of matrix means a film containing the active ingredients, and "the weight of backings" used in the present application correspond to the weight of the film only, and not to the weight of a film of matrix. Thus, the weight of the film only for the Cordes backings is within the following range:

Minimum: $96 \times 0.95 - 1.25$ (weight of estradiol) $- 8.32$ (weight of NETA) = 81.63

Maximum: $96 \times 1.05 - 1.25$ (weight of estradiol) $- 8.32$ (weight of NETA) = 91.23

Clearly, Cordes does not teach a polyester backing having the weight range from 100 to 130 g/m². Instead, Cordes only teaches a backing having a weight range from 81.63 to 91.23 g/m².

As such, the present invention is clearly distinguishable from the art cited in Tsuruda and Cordes. Consequently, the skilled artisan would not arrive at the present invention based on their disclosures, even in combination.

For all of the foregoing reasons, reconsideration and withdrawal of the rejection over Tsuruda and Cordes are requested.

Double-Patenting Rejection

Claims 1, 2, and 4-7 are non-provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 6, and 9 of U.S. Patent No. 6,924,410 (hereinafter "the '410 patent").

Applicants respectfully traverse the non-provisional double patenting rejection over claims 1-3, 6, and 9 of the '410 patent. It is submitted that claims 1-3, 6 and 9 of the '410 patent do not recite a patch having a backing of which ultraviolet transmittance is not more than 2.0% under the condition of 3.0 mW/cm² and the weight of the backing is within the range of 100 to 130 g/m². As previously discussed, the specific combination of the ultraviolet transmittance (measured under the specific condition) with the specific weight range of the backing is an important property of the instantly claimed patch, which makes the present invention patentably distinct over the patches claimed in the '410 patent. As such, the double patenting rejection over the '410 patent is believed to be overcome.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for immediate allowance.

FEE AUTHORIZATION

No fees are believed to be due. The Commissioner is authorized to charge any fees associated with this submission to our Deposit Account, No. 04-1105, Reference 64286(49811). Any overpayment should be credited to said Deposit Account.

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Respectfully submitted,

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